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| 10/524,892 | 03/21/2005 | Yoshiyuki Ueno | IPE-051 | 9982 |
| 20374 7590 09/25/2008 KUBOVCIK & KUBOVCIK SUITE 1105 1215 SOUTH CLARK STREET ARLINGTON, VA 22202 | | | | |
| EXAMINER | | | | |
| SYKES, ALTREV C | | | | |
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| 1794 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,892

Applicant(s)

UENO ET AL.

Examiner

ALTREV C. SYKES

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 19-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the objection to claims 1 and 6 in the last Office action mailed April 16, 2008 is noted and, therefore, the objection to those claims is withdrawn. In addition, examiner notes the addition of new claim 40. Further, examiner notes the amendment to claims 6 and 13 to provide for proper antecedent basis. As such, the 35 U.S.C. 112, second paragraph rejection has been withdrawn for those claims.

Response to Arguments

2. Applicant's arguments filed July 10, 2008 have been fully considered but they are not persuasive.
3. Regarding claims 1-5, 7,9-11,13-17 applicant argues that in the present invention a ratio of a soluble hydrophilic polymer to the total of the hydrophilic polymer in the modified substrate is 15 weight percent or less. However, in the Kasai reference a hydrophilic polymer is not crosslinked or insolubilized at all.

It is the position of the examiner that Kasai discloses vinyl alcohol-vinyl acetate hydrophilic copolymer may be deposited on the surface of the hydrophobic membrane which may be cross-linked by the use of dialdehyde or diisocyanate and further insolubilized in water. (See Col 6, lines 38-42) As such, it is noted by examiner that vinyl alcohol-vinyl acetate is also an insoluble copolymer. (See Col 3, lines 1-6) Therefore, in a membrane of Kasai a ratio of a soluble hydrophilic polymer contained in the hydrophilic polymer to the total of the hydrophilic polymer of the modified substrate

is automatically 15 weight percent or less because it would be zero since the Kasai reference does not require that the hydrophilic polymer contain any soluble hydrophilic polymer therein. Therefore, the claim limitation is met.

4. Applicant also argues that claims 6, 8, 12, and 18 are also patentable over Kasai et al. for the reasons given above that claim 1 is patentable. Examiner wishes to maintain the position as set forth above for claim 1 in regards to these claims also. The arguments are not found to be persuasive.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 7, 10-11, 13-17, 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Kasai et al. (US 4,776,959).

Regarding claims 1 and 40 Kasai et al. discloses a hydrophilic porous membrane which comprises a porous membrane of a hydrophobic polymer and a coating formed on at least one surface of the porous membrane and on the inner surface of the pores of the porous membrane with a water-soluble hydrophilic polymer soluble in a solvent exhibiting satisfactory stability and a satisfactory wetting property with respect to the hydrophobic polymer mentioned above. (See Col 2, lines 35-44) The porous membrane may also comprise a water-insoluble hydrophilic polymer. (See Col 2, lines 44-51) Kasai further discloses vinyl alcohol-vinyl acetate hydrophilic copolymer may be deposited on

the surface of the hydrophobic membrane which may be cross-linked by the use of dialdehyde or diisocyanate and further insolubilized in water. (See Col 6, lines 38-42) As such, it is noted by examiner that vinyl alcohol-vinyl acetate is an insoluble copolymer. (See Col 3, lines 1-6) Therefore, in a membrane of Kasai a ratio of a soluble hydrophilic polymer contained in the hydrophilic polymer to the total of the hydrophilic polymer of the modified substrate is automatically 15 weight percent or less because it would be zero since the Kasai reference does not require that the hydrophilic polymer contain any soluble hydrophilic polymer therein. Therefore, the claim limitation is met. Regarding the limitation that the number of adhered human blood platelets is $10/4.3 \times 10^3 \mu\text{m}^2$ or less when the modified substrate is brought into contact with human blood which contains heparin with a concentration of 50 U/mL at 37° C for one hour. It is noted by examiner that heparin is added to human blood as an anticoagulant, therefore, the number of adhered blood platelets would be minimal since the whole idea of adding the compound is to avoid clotting of the platelets. Additionally, Kasai discloses a membrane capable of use for artificial organs such as artificial kidney and blood plasma separation which means that the number of adhered human blood platelets to the modified substrate could very possibly be zero. (See Col 6, lines 43-50)

Regarding claims 2-5, 7, 10, 11, 13- 17 examiner maintains the rejection set forth in office action dated April 16, 2008.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai et al. (US 4,776,959) as applied to claim 1 above in view of Graiver et al. (US 5,429,839)

Regarding claim 6, examiner maintains the rejection set forth in office action dated April 16, 2008.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai et al. (US 4,776,959) as applied to claim 7 above in view of Nagatomo et al. (US 5,023,052).

Regarding claim 8, examiner maintains the rejection set forth in office action dated April 16, 2008.

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai et al. (US 4,776,959)

Regarding claim 9, Kasai et al. further discloses when the hydrophobic polymer is polyvinylidene fluoride, for instance, such examples include vinyl alcohol-vinyl acetate copolymers, random and block copolymers of vinyl pyrrolidone such as vinyl acetate-vinyl pyrrolidone copolymer, polyethylene glycol block copolymers such as polymethyl methacrylate-polyethylene glycol block copolymer, segmented polyurethane having

polyethylene glycol as a soft segment thereof, and block and random polyamino acids combining hydrophilic amino acids with hydrophobic amino acids. (See Col 5, lines 9-23) Apart from the top which bears directly on this invention, since the vinyl alcohol-vinyl acetate copolymer has desirable affinity for polyvinyl fluoride, a hydrophilic membrane may be produced by having the vinyl alcohol-vinyl acetate copolymer incorporated in a certain proportion into polyvinylidene fluoride during the production of a polyvinylidene fluoride membrane. When this method is adopted, it is enabled to vary the strength of a porous membrane and obtain a hydrophilic membrane answering the purpose of its use by simultaneously incorporating therein an additional polymer such as polymethyl methacrylate which has satisfactory affinity for polyvinyl fluoride and is capable of enhancing the hardness of the resin. (See Col 6, lines 24-37) Although, Kasai et al. does not specifically disclose the substrate comprises an anionic hydrophilic polymer and a nonionic hydrophilic polymer, the reference does disclose that an additional polymer may be added to the membrane to answer the purpose of its use. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the disclosure of Kasai et al. to add additional hydrophilic polymers thereby tailoring the substrate for end product use.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai et al. (US 4,776,959) as applied to claim 1 above in view of Ricketts et al. (US 2,715,091).

Regarding claim 12, examiner maintains the rejection set forth in office action dated April 16, 2008.

12. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi et al. (US 5,658,466) in view of Aoyagi et al. (US 4,609,464).

Regarding claim 18, examiner maintains the rejection set forth in office action dated April 16, 2008.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALTREV C. SYKES whose telephone number is (571)270-3162. The examiner can normally be reached on Monday-Thursday, 8AM-5PM EST, alt Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1254. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Carol Chaney/
Supervisory Patent Examiner, Art Unit 1794